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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/733,266 12/08/00 KUO

R STAN-209

HM22/0703

EXAMINER

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ART UNIT

PAPER NUMBER

1651

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/733,266

Applicant(s)
Kuo et al.

Examiner
Vera Afremova

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 11, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 6, 7, 10, and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 9, 11, and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: Notice to comply with SEB requirement

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DETAILED ACTION

Claims 1-18 are pending.

Election/Restriction

Applicant's election without traverse of the Group I invention drawn to an *in vitro* method of modulating oocyte activation (claims 1-5, 8, 9, 11 and 13-18) the in Paper No. 7 filed 6/11/2001 is acknowledged. Thus, the claims drawn to a nonelected invention of the Group II (claims 6, 7, 10 and 12 which are directed to an *in vivo* method of modulating oocyte activation) are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), there being no allowable generic or linking claim.

• Claims 1-5, 8, 9, 11 and 13-18 are under examination in the instant office action.
•

Claim Rejections - 35 U.S.C. § 112

Claims 1-5, 8, 9 and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8 and 9 are rendered indefinite by the phrase "administering" because this phrase appears to have a meaning of an *in vivo* application. The elected invention is drawn to an *in vitro* application. And, thus, this phrase fails to point the elected invention as claimed.

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Claim 2, 15 and 17 are rendered indefinite by the phrase "in combination with" fertilization or nuclear transfer because it is unclear whether a modulator of nitric oxide level is brought into contact with an oocyte before or after the event as intended.

Claims 5 and 8 are rendered indefinite by the use of abbreviations. Abbreviation in the first instance of claims should be explained upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 9, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grumetto et al. [U].

The claims are directed to a method of modulating activation of oocytes wherein the method comprises a step of contacting an oocyte with a modulator of nitric oxide (NO) level in an *in vitro* system. Some claims are further drawn to the use of a modulator such as NO donor or NO precursor. Some claims are further drawn to oocyte activation during fertilization.

Grumetto et al. [U] disclose a method of modulating activation of oocytes of the ascidian *Ciona intestinalis* wherein the method comprises a step of contacting an oocyte with a modulator

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of nitric oxide level or NO donor such as sodium nitroprusside in an *in vitro* system (abstract).
The reference further discloses modulation of NO level or oocyte activation during fertilization (Fig. 4).

The cited reference anticipate the present invention as claimed and as disclosed by application since the cited NO donor or NO precursor such as sodium nitroprusside is regarded as a suitable NO level modulator according applicants' definitions (page 6, lines 25- 27 and page 7, line 11) and the method of the present invention is related to oocytes derived from a wide variety of animal species including invertebrate (page 9, line 11).

Claims 1, 2, 3, 8, 10, 11, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Jawerbaum et al. [V].

The claims are directed to a method of modulating activation of oocytes comprising step of contacting an oocyte with a modulator of nitric oxide (NO) level in an *in vitro* system wherein the modulator is a donor of NO or a precursor of NO or an inhibitor of nitric oxide synthase (NOS). Some claims are drawn to contacting oocyte prior to fertilization. Some claims are further drawn to the use of mammalian oocytes.

Jawerbaum et al. [V] disclose a method of modulating activation of oocytes comprising step of contacting *in vitro* cultured and matured rat oocytes (page 392, par. 3, line 2) with a modulator of nitric oxide (NO) level such as NO donors and NOS inhibitors.

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The cited method is considered to anticipate the claimed method because both methods comprise identical step of contacting identical oocytes with identical modulators. The cited oocytes have been recovered from mammalian follicles and matured by *in vitro* hormone treatment as the applicants' oocytes as intended (see specification page 5, line 24-26).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 9 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grumetto et al. [U] taken with Jawerbaum et al. [V] and US 6,077, 710 [IDS-AB].

The claims are directed to a method of modulating activation of oocytes comprising step of contacting an oocyte with a modulator of nitric oxide (NO) level in an *in vitro* system wherein the modulator is a donor of NO or a precursor of NO or an inhibitor of nitric oxide synthase (NOS). Some claims are further drawn to the use of mammalian or human oocytes. Some claims are drawn to contacting oocyte prior to fertilization in order to provide parthenogenetic activation or future nuclear transfer.

The cited references by Grumetto et al. [U] and Jawerbaum et al. [V] are relied upon as explained above for the disclosure of a method of modulating activation of oocytes with NO level

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modulators. The references are lacking disclosure drawn to the use of human oocytes in the method for modulating oocyte activation. The cited references are silent with regard to the teaching drawn to parthenogenetic oocyte activation instead of fertilization for future nuclear transfer.

However, the cited reference by Grumetto et al. [U] teaches an induction of fertilization current or Ca^{2+} currents by modulation of NO level (abstract).

And the secondary reference US 6,077, 710 [IDS-AB] teaches that activation of oocytes is a function of calcium (Ca^{2+}) (col. 2, line 42) and that parthenogenic activation of oocytes prior to nuclear transfer and related to repetitive transient elevations in intracellular Ca^{2+} in mammalian oocytes (col. 2, lines 47-50 and col. 3, lines 5-10).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the present invention as claimed with a reasonable expectation of success in activating oocytes with NO level modulators because the prior art teaches that activation of oocytes and/or fertilization channels are modulated by NO levels [U] and activation of oocytes is related to Ca^{2+} fluctuations in oocytes including mammalian oocytes [IDS-AB]. The method of the present invention is related to activation of oocytes derived from a wide variety of animal species including invertebrate species, mammals and etc. (specification page 9, line 11) as demonstrated by the cited prior art [U, V, IDS-AB]. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

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The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103 and/or amounts of particular ingredients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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June 27, 2001.



SANDRA E. SAUCIER
PRIMARY EXAMINER

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Attachment to DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37CFR 1.821(a)(1) and (a)(2). For example: see specification page 14, line 14.

However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Failure to comply with these requirements will result in ABANDONMENT of the application under 37CFR 1.821(g). Applicant is requested to return a copy of the attached Notice to Comply with the response.

Appropriate correction is required.

V.A.